

A bill for an act

relating to health; changing provisions for handling genetic information from newborn screening; requiring a report; amending Minnesota Statutes 2008, sections 13.386, subdivision 3; 144.125, subdivision 3.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2008, section 13.386, subdivision 3, is amended to read:

Subd. 3. **Collection, storage, use, and dissemination of genetic information.** (a)

Unless otherwise expressly provided by law, genetic information about an individual:

(1) may be collected by a government entity, as defined in section 13.02, subdivision 7a, or any other person only with the written informed consent of the individual;

(2) may be used only for purposes to which the individual has given written informed consent;

(3) may be stored only for a period of time to which the individual has given written informed consent; and

(4) may be disseminated only:

(i) with the individual's written informed consent; or

(ii) if necessary in order to accomplish purposes described by clause (2). A consent to disseminate genetic information under item (i) must be signed and dated. Unless otherwise provided by law, such a consent is valid for one year or for a lesser period specified in the consent.

(b) Notwithstanding paragraph (a), the Department of Health's collection, storage, use, and dissemination of genetic information and blood specimens for testing infants for heritable and congenital disorders are governed by sections 144.125 to 144.128.

Sec. 2. Minnesota Statutes 2008, section 144.125, subdivision 3, is amended to read:

Subd. 3. ~~Objection of parents to test~~ Information provided to parents. ~~Persons with a duty to perform testing under subdivision 1 shall advise parents of infants (1) that the blood or tissue samples used to perform testing thereunder as well as the results of such testing may be retained by the Department of Health, (2) the benefit of retaining the blood or tissue sample, and (3) that the following options are available to them with respect to the testing: (i) to decline to have the tests, or (ii) to elect to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing. If the parents of an infant object in writing to testing for heritable and congenital disorders or elect to require that blood samples and test results be destroyed, the objection or election shall be recorded on a form that is signed by a parent or legal guardian and made part of the infant's medical record. A written objection exempts an infant from the requirements of this section and section 144.128.~~

(a) Prior to collecting a sample, persons with a duty to perform testing under subdivision 1 must provide parents or legal guardians of infants with a document that provides the following information:

(1) the blood sample will be used to test for heritable and congenital disorders, the blood sample will be retained by the Department of Health for a period of at least two years and that the blood sample may be used for public health studies and research;

(2) the data that will be collected as a result of the testing;

(3) the alternatives available to the parents set forth in paragraph (b) and that a form to exercise the alternatives is available from the person with a duty to perform testing under subdivision 1;

(4) the benefits of testing and the consequences of a decision to permit or refuse to supply a sample;

(5) the benefits of retaining the blood sample and the consequences of a decision to destroy the blood sample after two years or to permit or decline to have the blood sample used for public health studies and research;

(6) the ways in which the samples and data collected will be stored and used at the Department of Health and elsewhere; and

(7) the Department of Health's Web site address where the forms referenced in paragraph (b) may be obtained.

This document satisfies the requirements of section 13.04, subdivision 2.

(b) The parent or legal guardian of an infant otherwise subject to testing under this section may object to any of the following:

(1) the testing itself;

(2) the maintenance of the infant's blood samples and test result records for a period longer than 24 months; and

(3) the use of the infant's blood samples and test result records for public health studies and research.

If a parent or legal guardian elects one of the alternatives, the election shall be recorded on a form that is signed by the parent or legal guardian. The signed form shall be made part of the infant's medical record and shall be provided to the Department of Health. The signature of the parent or legal guardian is sufficient and no witness to the signature, photo identification, or notarization shall be required. When a parent or legal guardian elects an alternative under this subdivision, the Department of Health must follow the election and section 144.128. A written election exempts an infant from the requirements of this section and section 144.128.

(c) For purposes of this subdivision, "public health studies and research" includes calibrating newborn screening equipment, evaluating existing newborn screening tests to reduce the number of false positive and false negative results, studying the development of new newborn screening tests for heritable and congenital disorders, and other population-based health studies.

Sec. 3. **NEWBORN SCREENING REPORT.**

By January 15, 2010, the Department of Health shall report and make recommendations to the legislature on its current efforts for ensuring and enhancing how parents of newborns are fully informed about the newborn screening program and of their rights and options regarding: (1) testing; (2) storage; (3) public health practices, studies, and research; (4) the ability to opt out of the collection of data and specimens related to the testing; and (5) the ability to seek private testing.